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(72) Inventor: **Nierich, Arno Pieter**
Hattem 8051 CJ (NL)

(74) Representative: **Metman, Karel Johannes et al**
De Vries & Metman
Overschiestraat 180
1062 XK Amsterdam (NL)

(71) Applicant: **Gelanus B.V.**
8051 CJ Hattem (NL)

(54) **Blood recuperation device and method**

(57) A blood filtering device (1) for the recuperation of blood from wound drained blood, in particular for an autologous blood transfusion system, has a first filter (7) arranged upstream of a second filter (8), the first filter (7) being adapted for removing emboli and/or large particulate matter from the blood and for allowing red blood cells to pass, the second filter (8) being adapted for retaining red blood cells, an exit port (6) arranged downstream of the first filter (7) and upstream of the second filter (8). The device is characterised in that the second filter (8) has a pore size of more than about 0.5 μm . A method of recuperating blood from wound drained blood is also disclosed.

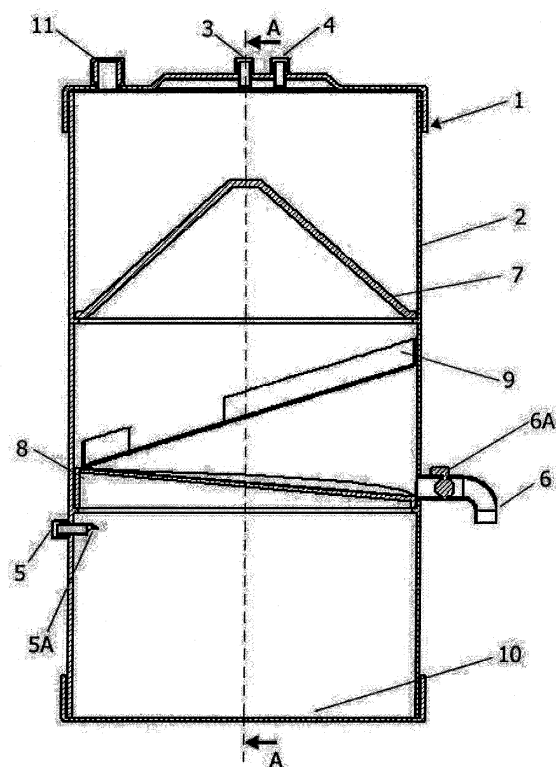


Fig. 1

Description

[0001] The present invention pertains to a blood filtering device and a method for the recuperation of blood from wound drained blood, in particular for an autologous blood transfusion and a system therefor, the filtering device comprising an entrance port for the blood, a first filter and a second filter, wherein the first filter is arranged upstream of the second filter, the first filter adapted for removing emboli and/or large particulate matter from the blood received through the entrance port and for allowing red blood cells to pass, the second filter adapted for retaining red blood cells and an exit port arranged between the first and second filter, i.e. downstream of the first filter and upstream of the second filter.

[0002] After a patient has undergone an operation, specific wounds, e.g. thorax wounds after cardiac operations, may be provided with drains to remove the wound secretions, which fluid usually comprises blood. A patient may lose so much blood that he/she requires a blood transfusion. Autologous blood transfusion, the reinfusion of a patient's own blood, minimises risks linked to blood transfusions with blood donated by other people, so-called homologous blood transfusions, viz. anaphylactic reactions and/or donor-associated infections such as hepatitis, acquired immune deficiency syndrome (AIDS), adverse effects HLA (human leucocytes antigens), and malaria.

[0003] For an autologous blood transfusion, the fluid comprising the lost blood must be collected and the blood to be reinfused must be recuperated therefrom. This blood which preferably is as rich as possible in healthy red blood cells or erythrocytes, must be filtered out of the drained blood and freed or washed from impurities and/or contaminants before reinfusion. Typical impurities in blood drained from a recovering wound site are, among others, bone and tissue fragments, blood clots and fat particles, as well as activated coagulation factors, plasma free haemoglobin, denaturated proteins, platelets, leucocytes and lipids.

[0004] The purification of autologous blood, generally called "washing", is usually performed in two steps: first the drained fluid is filtered relatively coarsely to remove large particulate debris and impurities from the blood, next the filtrate is mixed with a "washing fluid", usually a saline solution or Ringer's solution, put in a centrifuge chamber for separation of the relatively heavy blood cells from the blood plasma and relatively light and small particles such as platelets, plasma proteins and antibodies. The recovered blood is generally reinfused under low pressure through a leukocyte filter for further reducing the number of remaining white blood cells in the transfused blood.

[0005] This cell washing technique works only for batches. Further, during washing by the centrifuge-process, significant numbers of the collected red blood cells become damaged and are lost to the patient. This method depends on complex equipment that is not available

when the blood loss is over an extended period of time, e.g. 6-12 hours, on a non operating room such as an Intensive Care Unit (ICU).

[0006] An improvement to this technique is provided by using a two-step filtering system which may be used for continuous or quasi-continuous washing of wound drained blood. Such a filter system, having the features of the introductory part of claim 1, is e.g. known from EP 0 518 975, which discloses an apparatus for recycling autologous blood from a patient for reinfusion back to the patient comprising suction means, admixing means for admixing aspirated blood with a washing fluid, filtering means for filtering the admixture through an emboli filter and a membrane filter, monitoring means for measuring the amount of cellular component volume in the filtered blood, filtration means for removing excess fluid and particulates from the blood, and reinfusion means. The membrane filter may be any conventional membrane-type separator with a pore-size ranging from 40 000 daltons to 400 000 daltons molecular weight cut-off. However, if larger impurities are to be removed, a plasma filter having a pore size larger than about 400 000 daltons, and up to 0.4 μm , can be used.

[0007] In order to achieve filtering of the blood from small impurities through such commercially available membrane filters, experiments have proven that only blood having a blood cellular volume, or haematocrit, of less than about 25 % and an applied pressure difference across the membrane filter of more than about 400 mm Hg should be used. Furthermore, the filters tend to clog, requiring an even higher pressure difference and/or an even lower haematocrit for operation. These devices can also work only if strong anticoagulation by medication such as heparin is used during filtering.

[0008] It is desired, in particular for severely weakened patients such as those stationed on an intensive care ward, to have a simple, reliable filtering device which may yield purified blood with a high haematocrit value, e.g. 70 % or even higher, for autologous blood transfusions. This will enhance recovery of the patient and reduce morbidity and mortality.

[0009] Further, systems capable of reaching the necessary relatively high pressure difference, i.e. moderate to high vacuum sources or roller pumps may be unavailable in some hospitals, especially in less-developed countries.

[0010] Moreover, it has become apparent that the autologous blood prepared according to the prior art may still comprise impurities such as fractured red blood cells, activated platelets or activated tissue factors, which may cause complications to the patient such as inflammation reactions.

[0011] It is therefore an object of the present invention to provide an improved blood filtering device and a method, for the recuperation of blood from wound drained blood which substantially alleviates such problems of the prior art.

[0012] To that end, the second filter has a pore size of

more than about 0.5 μm . Thus, since red blood cells tend to have an average size of about 4 μm and may form small chains or clumps of up to about 10 μm , a filter device according to the present invention provides a filtering means to filter out relatively large impurities and to let healthy red blood cells pass through the first filter, whereas the second filter retains these cells and lets fluid and smaller impurities and/or contaminants pass.

[0013] The larger pore size of the second filter, compared to the prior art, provides a relatively low fluid flow resistance, so that the device may operate with low or no applied pressure difference across the filter and so that excess fluid, e.g. washing fluid or irrigation fluid, may be filtered out effectively.

[0014] Thus a relatively simple device is achieved which provides a filtering window for recuperating red blood cells with minimum additional equipment being necessary.

[0015] The pore size of the second filter may be in the range of about 1-10 μm , preferably in the range of about 2-8 μm , more preferably in the range of about 4-6 μm , e.g. 5 μm . Selecting a size in this range enables an accurate tuning of the filtering window to retain healthy red blood cells, but to filter out also relatively large impurities.

[0016] Such a relatively coarse second filtering step, compared to the prior art, may cause some beneficial factors of the blood to be filtered out and be lost, such as blood platelets. However, most of these platelets are activated and their quantity is mostly low since most will remain into the wound itself in order to reach coagulation at the site of tissue trauma. Thus, the additional reduction of noxious impurities such as other tissue factors and the easy handling of the present invention are considered to substantially outweigh this effect, rendering the present filtering device and method a clear improvement over the prior art.

[0017] According to the invention, the first filter may have a pore size of less than about 200 μm , preferably less than about 100 μm , e.g. 50 μm to obtain an efficient filtering action in the first filtering step.

[0018] The invention also includes a method of recuperating blood from wound drained blood, in particular for an autologous blood transfusion, comprising the steps of aspirating or collecting wound drained blood of a patient in a conduit, filtering the blood from the conduit in a first relatively coarse manner for removing emboli and/or particulate matter from the blood, filtering the coarsely filtered blood in a second relatively fine manner for filtering out small impurities and/or liquid from the blood and retaining red blood cells in the residue, collecting the residue of the second filtering step, the second filtering step being performed to retain particles having a size of more than about 0.5 μm and to remove smaller particles therefrom.

[0019] The second filtering step may be performed to filter out and retain particles having a size of more than about 1 μm , preferably more than about 2 μm , preferably more than about 4 μm , e.g. about 5 μm , and to remove

smaller particles therefrom, and preferably the first, relatively coarse, filtering step is performed to filter out particles having a size of more than about 200 μm , preferably more than about 100 μm , e.g. more than 50 μm .

[0020] The invention moreover includes a kit, comprising a blood filtering device as described above, a conduit for draining wound secretions, and a blood receptacle, all packed under sterile conditions, as well as an autologous blood transfusion assembly.

[0021] The invention and its operation will become clearer from the following drawings which show a non limiting exemplary embodiment of the device according to the invention.

[0022] Fig. 1 is a cross sectional view of a blood filtering device for the recuperation of blood from wound drained blood.

[0023] Fig. 2 is a cross sectional view of the blood filtering device perpendicular along the line AA to the view of Fig. 1.

[0024] Fig. 3 is a larger scale perspective view of a second filter, suitable for use in the filtering device of Fig. 1.

[0025] Figs. 1 and 2 show a filtering device 1, comprising a generally tubular housing 2, provided with a connection 3 for introducing blood to the device, an optional connection 4 for a source of washing fluid, an optional vacuum connector 5 and an exit port 6 provided with a valve 6A for removing recuperated blood. Inside the housing 2 a first filter 7, a second filter 8 and a baffle 9 are arranged. The housing 2 further comprises a reservoir 10 for waste filtrate and an underpressure safety valve 11. The entrance 5A of the vacuum conduit 5 is oriented away from the second filter to prevent it from aspirating waste filtrate.

[0026] The connections 3, 4, 5 and the exit port 6 are preferably provided with connectors such as standard size Luer Lock connections. Alternatively, the connections may have drains and/or conduits fixedly attached thereto.

[0027] The underpressure safety valve 11 is preferably a microporous hydrophobic filter unit which is capable of passing gasses therethrough but no liquids, but may also be realised differently in any known way.

[0028] Preferably the filter device 1, a set of drains and conduits and possibly one or more blood receptacles and a quantity of washing fluid are provided in a single, preferably sterile packed, kit which may also comprise appropriate means for application of the drain, so that a complete treatment assembly is conveniently provided. The used parts are preferably adapted to be disposable, to prevent inadvertent re-use for another patient or other known blood-related biohazards.

[0029] For recuperating blood from wound drained blood with the filtering device 1, a blood receptacle is connected to the exit port 6. The blood receptacle may be an evacuated blood bag, a blood bag with washing or preserving liquid or any other suitable device. It may also be a blood reinfusion device for direct on-line reinfusion

of the blood.

[0030] Next, the drain 3 is applied to the wound site in any known appropriate manner, and the drained blood - comprising impurities - is introduced into the filtering device 1 through the connection 3.

[0031] The device may be used in the clinical situation, connected to the patient wound-site or independently, i.e. disconnected from a patient, to filter collected wound drained blood.

[0032] In the former situation, a fluid-filled drain may simply siphon the wound drained blood under influence of gravity from the wound site to the filtering device when it is placed lower than the wound site, e.g. on the ground next to the patient's bed. The draining may be assisted by aspiration by means of a low vacuum inside the filtering device, e.g. derived from an evacuated blood bag, or derived from a vacuum source connected with the vacuum connection 5, e.g. using a vacuum pressure of -30 cm H₂O.

[0033] In the latter situation, the filtering may be assisted by means of a deeper vacuum, which is preferably less than -200 mm Hg, e.g. -120 mm Hg.

[0034] Upon introduction into the filtering device 1, emboli and/or relatively large particulate impurities are removed from the wound drained blood by the first filter 7 and smaller particles, including red blood cells are passed through the first filter 7. Via the baffle 9 the blood is supplied to the second filter 8.

[0035] The second filter 8 serves to retain the red blood cells and to filter out smaller impurities left in the blood after the first filtering step. The residue of the second filter 8 is collected at the exit port 6 and the filtrate is received in the reservoir 10 and is considered a waste product of the process.

[0036] As is clearly visible, in the embodiment of Figs. 1 and 2, the first filter 7 has a top (upstream) surface, which is convex, tapering in the upstream direction. This shape causes the incoming drained blood to flow off to the sides of the filter 7 where residue may be amassed, leaving the central portion of the filter surface essentially clear. Thus, this feature prevents clogging of the first filter 7 to a large degree and allows to use a smaller pore size than the customary 40 µm, e.g. down to about 15 µm, to remove smaller debris if so desired. However, a larger pore size than 40 µm allows faster filtering and reduces the need for applying a pressure difference across the filter, such as by means of a vacuum.

[0037] A concave-shaped first filter 7 can also be used. This has the effect that the residue is amassed at or near the bottom of the filter, where it may act as an additional filter material which may reduce the filtering speed and -yield, but at the same time may cause the filtrate to be of a higher quality, i.e. containing less impurities.

[0038] The second filter 8 has a main surface orientation at an angle to the horizontal (Figs. 1-3). The exit port 6 is located at least near the relatively lowest point or edge of the second filter. This causes the blood to flow across the surface of the second filter 8 towards the exit

port 6 under the influence of gravity.

[0039] The baffle 9 is arranged at an angle to the horizontal and is provided with three apertures near its lower side (Fig. 2). Thus, the baffle 9 serves to direct the blood to the relatively high sides of the second filter 8 to use the maximum path length for filtering.

[0040] The overall selectivity of the second filter 8 is determined by its pore size and the effectively filtered quantity is determined to a certain extent by the filtration time.

[0041] The duration of the second filtering step is mainly determined by the flow velocity of the blood across the filter surface of a given size. The flow velocity is inter alia determined by the combination of the angle of the filter with respect to the horizontal, the viscosity of the blood and the roughness or smoothness of the upstream surface of the filter 8. The filtration time may be adapted by opening or closing of the valve 6A.

[0042] A suitable filter may have an upstream surface which is, apart from the pores, substantially smooth at a micron size scale, preferably at a sub-micron size scale, e.g. such that the surface has a shiny appearance. The filter may have a hard surface, or may also be a woven mesh filter of smooth filaments, e.g. of the type used for filtering beer. Such a smooth filter surface appears to leave red blood cells substantially intact and to reduce the probability of tangling and trapping of red blood cells in the filter material.

[0043] An angle of the main surface orientation of the second filter 8 to the horizontal of more than about 15 degrees usually provides insufficient filtration with such a smooth filter, as the blood then flows down to the exit port 6 essentially unfiltered. An angle of about 6 degrees provides proper filtering of impurities, yet may leave fluid, such as washing fluid or irrigation fluid in the residue. An angle of about 3 degrees (Figs. 1-4) provides effective filtering of both impurities and of fluids.

[0044] To direct the blood which is being filtered by the second filter 8 more efficiently to the exit port 6, the upstream surface of the filter is provided with guiding features, such as folds or side facets which are applied to or extend from the main surface as indicated more clearly in Fig. 5. Similarly, the filter surface may be provided with structures to spread the blood to be filtered more evenly across the filter surface, if so desired.

[0045] Washing liquid, e.g. a saline solution or Ringer's solution with a bolus dose of an anticoagulation drug such as heparin, may be introduced in the device to flush the filters 7, 8 and the intermediate baffle 9 and/or to assist the blood cells to collect at the bottom of the second filter 8.

[0046] The blood and the washing liquid are preferably introduced in the filtering device 1 relatively close to the centre of the first filter 7. This arrangement causes the fluids to flush and keep clear the first filter 7 to reduce clogging thereof and to retrieve as many red blood cells as possible.

[0047] When a washing fluid is used, some of it may

be collected in the blood receptacle and not be filtered out. However, with the proper choice of washing fluid, e.g. a saline solution or a Ringer's solution, the quality of the red blood cells is unaffected.

[0048] It is believed that, without wishing to be bound to any specific theory, a reduced temperature reduces the ability and/or likelihood of the red blood cells to flex and to pass through smaller openings than the diameter of a red blood cell at rest, and even might prevent a red blood cell from passing through an opening which is slightly larger than its diameter. The natural reduction from body temperature to ambient room temperature, i.e. from about 37 degrees Celsius to about 20 degrees Celsius, already causes a substantial increase in the efficiency of the filter, as less blood cells pass therethrough.

[0049] A filtering device according to the present invention may be used for several hours on end, during which the filtered blood may be left in the device, on the second filter or the blood may be collected in a blood receptacle.

[0050] The residue of the second filter 8, comprising the recuperated blood cells may also comprise white blood cells or leukocytes having the same size as the red blood cells. These leukocytes should preferably be removed before reinfusion of the blood, which can efficiently be done by passing the autologous blood through a commercial leukocyte filter (Pall filter).

[0051] Due to its relative simplicity, and due to the fact that no complicated additional apparatus such as pumps are required for the operation of the filtering device 1, the device 1 may be produced and/or used relatively cost-effectively. This makes the filtering device very well suited for use in poorer and/or less-developed countries, where the risks of infections or diseases, particularly AIDS, from a homologous blood transfusion are much higher than in more-developed countries.

[0052] The invention is not restricted to the above described embodiments which can be varied in a number of ways within the scope of the claims. For instance, additional filters or devices may be used or added for recuperating other blood products, such as intact platelets or blood plasma, from the filtrate of the second filter. The first and second filter may also be provided in different housings.

[0053] Further, the first and/or second filter may be made from a filtering material which does not solely function on a size cut-off, but which also provides a filtering action based on biophysical or biochemical properties, such as (a-)polarity of the particles to be filtered out or retained.

[0054] Further, the directing function of the baffle may also be fulfilled by a funnel, a conduit or by generally shaping the housing 2 appropriately, e.g. providing it with a sloping side and arranging the first and second filters 7, 8, offset from another.

Claims

1. Blood filtering device (1) for the recuperation of blood from wound drained blood, in particular for an autologous blood transfusion system, comprising an entrance port (3) for the blood, a first filter (7), a second filter (8), wherein the first filter (7) is arranged upstream of the second filter (8), the first filter (7) being adapted for removing emboli and/or large particulate matter from the blood received through the entrance port (3), and for allowing red blood cells to pass, the second filter (8) adapted for retaining red blood cells, and an exit port (6) arranged between the first and second filter (7,8), i.e. downstream of the first filter (7) and upstream of the second filter (8), **characterised in that** the second filter (8) has a pore size of more than about 0.5 μm .
2. Blood filtering device (1) according to claim 1, wherein the pore size of the second filter (8) is in the range of about 1-10 μm , preferably in the range of about 2-8 μm , more preferably in the range of about 4-6 μm , e.g. 5 μm .
3. Blood filtering device (1) according to claim 1 or 2, wherein the first filter (7) has an upstream surface which is generally convex or concave in the upstream direction, such as spherical, conical, or tapering.
4. Blood filtering device (1) according to any one of the preceding claims, wherein the second filter (8) has an upstream surface which is substantially smooth at a micron size scale, preferably at a sub-micron size scale, e.g. such that the surface has a shiny appearance.
5. Blood filtering device (1) according to any one of the preceding claims, wherein the second filter (8) has a main surface orientation at an angle to the horizontal, preferably in a range between 0 and 15 degrees, more preferably between 0 and 6 degrees, e.g. about 3 degrees, and wherein the exit port (6) is located at least near the relatively lowest point or edge of the second filter (8).
6. Blood filtering device (1) according to any one of the preceding claims, wherein the device (1) is adapted for supplying the blood to the second filter (8) at least near the relatively highest point or edge of the second filter (8), e.g. by having a conduit, a baffle (9) or a funnel.

7. Blood filtering device (1) according to any one of the preceding claims, further provided with means (5) for connecting a relatively low vacuum source, e.g. of -120 mm Hg, to the device (1), preferably located downstream of the second filter (8). 5
8. Blood filtering device (1) according to any one of the preceding claims, further provided with a connector (4) for connecting a source of washing liquid thereto, preferably located upstream of the first filter (7). 10
9. Blood filtering device (1) according to any one of the preceding claims, wherein the device (1) is adapted to be disposable after single use. 15
10. Kit, comprising a blood filtering device (1) according to any one of the preceding claims, a conduit for draining wound secretions, and a blood receptacle, all packed under sterile conditions. 20
11. Autologous blood transfusion assembly comprising a blood filtering device (1) for the recuperation of blood from wound drained blood, in particular for an autologous blood transfusion system, comprising an entrance port (3) for the blood, a first filter (7) and a second filter (8), wherein the first filter (7) is arranged upstream of the second filter (8), the first filter (7) being adapted for removing emboli and/or large particulate matter from the blood received through the entrance port (3) and for allowing red blood cells to pass, the second filter (8) adapted for retaining red blood cells, an exit port (6) arranged between the first and second filter (7,8), i.e. downstream of the first filter (7) and upstream of the second filter (8), wherein the second filter (8) has a pore size of more than about 0.5 μm . 25
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12. Method of recuperating blood from wound drained blood, in particular for an autologous blood transfusion, comprising the steps of aspirating or collecting wound drained blood of a patient in a conduit, filtering the blood from the conduit in a first relatively coarse manner for removing emboli and/or particulate matter from the blood, filtering the coarsely filtered blood in a second relatively fine manner for filtering out small impurities and/or liquid from the blood and retaining red blood cells in the residue, collecting the residue of the second filtering step, **characterised in that** the second filtering step is performed to retain particles having a size of more than about 0.5 μm and to remove smaller particles therefrom. 45
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13. Method according to claim 12, wherein the second filtering step is performed to filter out and retain particles having a size of more than about 1 μm , preferably more(than about 2 μm , preferably more than about 4 μm , e.g. about 5 μm , and to remove smaller particles therefrom, and preferably the first, relatively coarse, filtering step is performed to filter out particles having a size of more than about 200 μm , preferably more than about 100 μm , e.g. more than 50 μm .
14. Method according to claim 12 or 13, wherein the duration of the second filtering step is determined by setting the second filter at a predetermined main angle to the horizontal and by supplying the blood to the second filter at least near its highest point or edge and allowing the blood to flow down across this filter to an exit thereof.
15. Method according to claim 14, wherein a washing fluid is used to expedite the filtering and/or (to assist) to collect the blood cells.
16. Method for performing an autologous blood transfusion comprising the method according to any one of the claims 12-15, or using a blood filtering device according to any one of the claims 1-9.

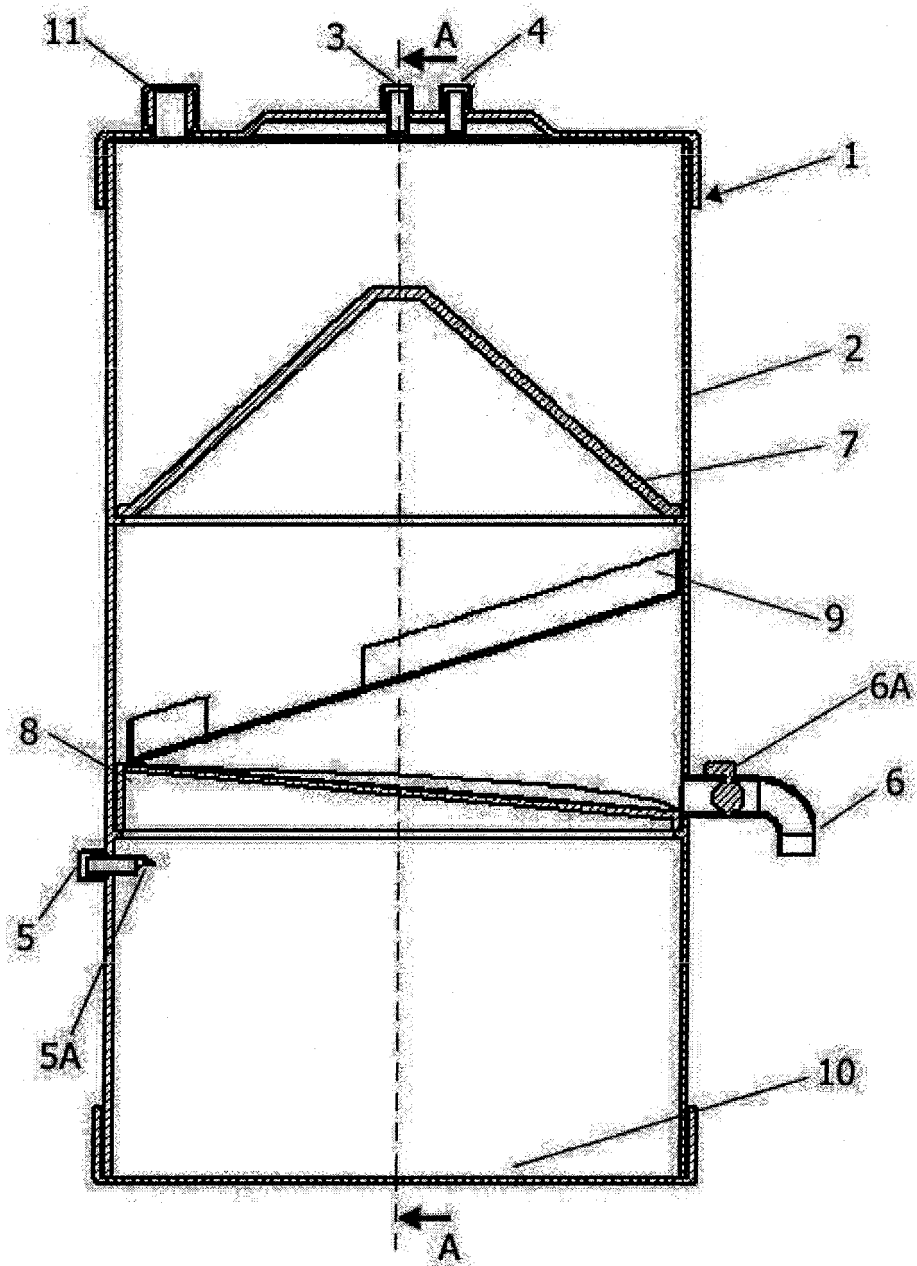


Fig. 1

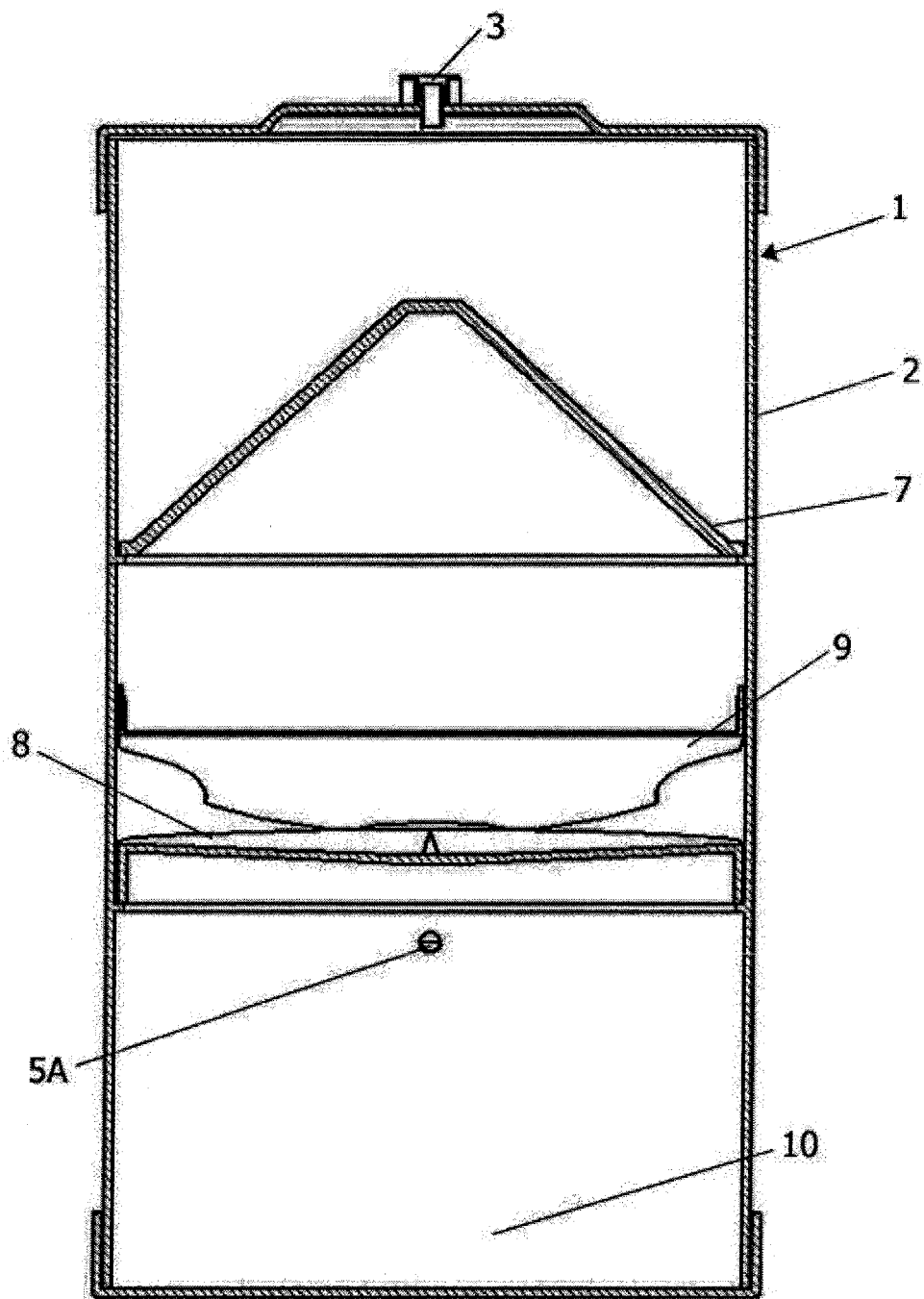


Fig. 2

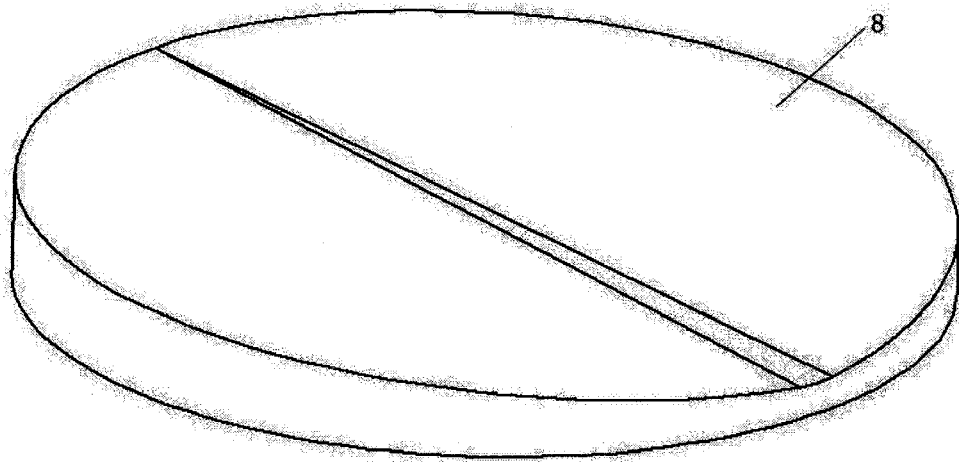


Fig. 3



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PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention EP 06 12 0396 shall be considered, for the purposes of subsequent proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT			
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INCOMPLETE SEARCH			
The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims. Claims searched completely : Claims searched incompletely : Claims not searched : Reason for the limitation of the search: see sheet C			
Place of search Munich		Date of completion of the search 19 February 2007	Examiner BICHLMAYER, K
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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EPO FORM 1503 03/82 (P04C07)



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**INCOMPLETE SEARCH
SHEET C**

Application Number

EP 06 12 0396

Claim(s) not searched:
16

Reason for the limitation of the search (non-patentable invention(s)):

Article 52 (4) EPC - Method for treatment of the human or animal body by surgery

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 06 12 0396

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
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19-02-2007

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